

**REMARKS**

Reconsideration is requested.

Claims 1-28 are pending. Claim 14-28 have been added and find support, for example, in the specification at pages 15-16 and page 57, lines 11-18. No new matter has been added.

The Examiner interviews of March 5, 2004 and May 20, 2004, are acknowledged, with appreciation. The Interview Summary from each are accurate in their brief description of the issues discussed. As noted above, the Office Action of March 12, 2004 is understood to have replaced the Office Action of February 19, 2004, such that the due date for responding was re-set from the mail date of the March 12, 2004, Office Action.

As confirmed with the Examiner during the interview of May 20, 2004, the elected species of the Examiner's required Group B is not an example of the elected species of the Examiner's required Group A. Any confusion caused by the applicants previous remarks in this regard are regretted and were inadvertent. The applicants regret any inconvenience caused by the same.

As also discussed with the Examiner during the May 20, 2004 interview, the undersigned is unclear as to the extent of the search to date as the Office Action of March 12, 2004 (Paper No. 0304) has maintained the restriction requirement, made the restriction requirement final, and also rejected claims 1-5, 10 and 11 for an alleged lack of enabling support across the full breadth of the claims and claims 1-13 for allegedly being obvious. The Examiner therefore appears to have examined the full breadth of the claims, without regard to the elected species. Perhaps the Examiner has not found

one or both of the elected species unpatentable over the prior art and has expanded the search beyond the elected species to the generic claims. Confirmation of the same however is requested in the Examiner's next Communication.

Claim 2 has been amended to obviate the objection of the same stated on page 3 of Paper No. 0304. Withdrawal of the objection of claim 2 is requested.

The specification has been amended to obviate the objection of the same stated on page 3 of Paper No. 0304. Withdrawal of the objection of the specification is requested.

The Section 112, first paragraph "enablement", rejection of claims 1-5, 10 and 11, is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following and the attached.

As discussed with the Examiner during the interview of May 20, 2004, the presently claimed invention provides a method which employs only those individual alleles at genetic loci that are known to be associated with increased or decreased susceptibility, as determined from reasonably credible evidence reported in peer reviewed scientific journals or articles. Moreover, the information of step (ii) of claim 1, for example, which matches each risk factor with at least one lifestyle recommendation are similarly determined from reasonably credible evidence reported in peer reviewed scientific journals or articles. Attached is a copy of the applicants "Cellf Nutrition Panel Technology White Paper", Version 1.24, 16 January 2004, which was discussed with the Examiner during the interview of May 20, 2004, and contains a compilation of scientific research which may be used as a basis for practicing the presently claimed invention. While the attached has not been publicly available, the information compiled

therein has been available from the noted sources. Moreover, as research continues, the datasets may be expanded to include new information.

The applicants explained during the interview of May 20, 2004, that the presently claimed invention provides a specific group of alleles for the claimed datasets, i.e., those which are known to satisfy the conditions of the claims. See, page 5 of Paper No. 0304. Moreover, in response to the Examiner's query as to whether the "instant invention [would] work with any known dataset of alleles?" (id.), the applicants noted during the interview that the claimed method could be practiced, without undue experimentation, with any known dataset of alleles which satisfied the conditions of subparagraphs (i) and (ii) of claims 1 and 14 (i.e., alleles known to have a correlation between the presence of the allele at genetic loci with a lifestyle risk factor and a known match or correlation between the risk factor and at least one lifestyle recommendation). Attached is a copy of the bound version of the "Personal Nutri-Genetic Analysis" shown to the Examiner during the interview of May 20, 2004, as well as an unbound copy, to make it easier for the Patent Office to scan the same and hopefully assure delivery of at least one copy to the Examiner. The "Personal Nutri-Genetic Analysis" is an example of the result of a commercial use of an embodiment of the claimed method produced by the applicants' Assignee.

Finally, attached are copies of the articles from the magazine Red and various newspapers and magazines, which were briefly discussed with the Examiner during the interview of May 20, 2004. These articles and news reports relating to the applicants' Assignee's activities are also listed on the attached PTO-1449 Form.

The applicants respectfully submit that the claims are supported by an enabling disclosure. Reconsideration and withdrawal of the Section 112, first paragraph "enablement", rejection of claims 1-5, 10 and 11 are requested.

The Section 112, second paragraph, rejection of claims 1-13 is obviated by the above amendment. Reconsideration and withdrawal of the Section 112, second paragraph, rejection of claims 1-13 are requested.

The Section 103 rejection of claims 1-13 over Brown (U.S. Patent No. ,985,559) and Perera (Carcinogenesis (2000) volume 21, pages 517-524) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

As discussed with the Examiner during the May 20, 2004, interview, it is not clear from Brown, for example, how one is to provide a dataset containing information matching a lifestyle risk factor with at least one lifestyle recommendation, according to the presently claimed invention, and how, for example, at least one lifestyle recommendation based on the identified risk factor is to be determined to generate a personalized lifestyle advice plan based on the lifestyle recommendations. That is, Brown provides examples of cystic fibrosis and Gaucher disease, as alleles of genetic loci of the human subject. The Examiner will appreciate that these diseases are inherited genetic disorders for which personalized treatment, as recited in the present invention, is not likely to be available. See, column 5, lines 51-54 and column 6, lines 25-29 of Brown. While Brown asserts that such a "personalized treatment for the patient can be developed", Brown does not provide any examples of such plans or a description of how such plans may be designed. The applicants respectfully submit that

Brown fails to teach or suggest a realistic embodiment of the presently claimed invention.

Perera is not believed to cure the deficiencies of Brown and withdrawal of the Section 103 rejection is requested.

For completeness, the applicants submit that Perera provides, at best, an invitation to further develop means to produce a lifestyle plan, without recommending any means or expectation of success to do so. Rather, Perera provides, for example, at page 521 that “Although epidemiological studies suggest that nutritional factors play a causative role in >30% of human cancers, the precise roles of specific dietary factors are uncertain and often controversial.” (Emphasis added.) Moreover, the remaining passage of the paragraph of Perera quoted by the Examiner in Paper No. 0304 indicates that the suggested methods are speculative at best. Such “obvious-to-try” teachings are not sufficient to support a *prima facie* case of obviousness.

Withdrawal of the Section 103 rejection of claims 1-13 is requested.

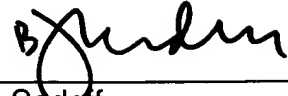
The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is invited to contact the undersigned in the event anything further is required in this regard.

GILL-GARRISON et al.  
Appl. No. 09/771,933

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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